REMARKS

This response addresses the issues raised by the Examiner in the Office Action mailed March 22, 2004. Initially, Applicants would like to thank the Examiner for the careful consideration given in this case. The Claims were 2-3. Claim 2 has been currently amended and Claim 4 has been added. Thus, Claims 2-4 are pending in this case all to more clearly and distinctly claim Applicants' invention. New Claim 4 introduces no new matter and is fully supported by the specification. Applicants respectfully request entry of the amendments as they place the application in condition for allowance or in better condition for possible appeal.

New Claim 4 has been added and claims a method of measuring a blood component in a dry analytical process using a dry analytical element and a control serum where the fibrin has been removed in the presence of calcium ions. New Claim 4 depends appropriately from Claim 2. Support for new Claim 4 appears, for example, in the specification at page 1, lines 23-25. Accordingly, it is respectfully submitted that no new matter has been added by the amendments.

Rejection Based On 35 U.S.C. § 112, Second Paragraph

The Examiner rejects Claims 2-3 under 35 U.S.C.§112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. More specifically, the Examiner asserts that claim 2 is indefinite because is it not clear when the blood component is measured in the serum and if dialysis is performed on the serum before or after the step of freezing or freeze drying. Applicants respectfully traverse this rejection.

Since Claim 2 has been currently amended, Applicants will address Examiner's rejection with regards to currently amended Claim 2. In order to expedite prosecution, Claim 2 has been amended to clarify that the method of measuring a blood component in a dry analytical process using a dry analytical element and a control serum where the control serum is prepared from a serum from which fibrin has been removed but which has not been subjected to dialysis by freezing or freeze drying. This shows that the serum of the invention is not a sample but a control serum. For example, when the sample is a serum, two sera are used, one is the sample serum and the other is the control serum of the present invention. The analytical value of the sample is determined in comparison with the data of the control serum.

Further, no dialysis is performed on the serum before or after the step of freezing or freeze drying. Support for currently amended Claim 2 appears, for example, in the Specification at page 1 at lines 23-26, page 3 at lines 23-27 and pages 10-11 at lines 26-27 and 1-2, respectively. Further, Claim 3 depends from Claim 2 and as such includes the limitations of Claim 2. Therefore, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. § 112, second paragraph.

Rejection Based On Yanagihara Under 35 U.S.C. § 102 (b)

The Examiner rejects previously pending Claims 2-3 under 35 U.S.C. § 102 (b) as being anticipated by U.S. Patent 4,368,275 to Yanagihara et al. as applied to currently amended Claim 2. Applicants respectfully traverse this rejection.

The Examiner asserts that Yanagihara teaches a dry analytical element in the form of a dry gel chromatographic packing. The Examiner also states that Yanagihara teaches a method in which a sample solution of a freeze dried human control serum is applied to the dry gel chromatographic packing material in a column. The analytes of albumin, creatinine and uric acid are analyzed in the control serum upon eluting through the column. Although the Examiner concedes that Yanagihara does not mention that the freeze dried control serum undergoes any dialysis process, the Examiner concludes that Yanagihara anticipates the present invention.

To establish obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. MPEP § 2143.03. Yanagihara discloses a granular cross-linked copolymer as a high speed liquid chromatography packing, such as gel permeation chromatographic packing. See Abstract. However, the dry gel permeation chromatographic packing of Yanagihara is not a dry analytical element used in a dry process. This is because Yanagihara uses a liquid chromatography. Yanagihara does not disclose, teach or suggest a method of measuring a blood component in a dry analytical process. Since the gel permeation chromatography of Yanagihara belongs to a wet process, the problems solved in the present invention do not exist in Yanaguhara. Although Yanagihara discloses a freeze dried human serum, Yanagihara does not even mention dialysis. This is unlike the present invention in which the control serum is a commercial product that has been dialyzed. See Specification at page 2, lines 7-9.

In contrast, the present invention claims a method of measuring a blood component in a dry analytical process using a dry analytical element and a control serum where the control serum is prepared from a serum from which fibrin has been removed but which has not been

subjected to dialysis by freezing or freeze drying. The purpose of the present invention is to provide a control serum which enables quantitative results in dry analytical processes for tests necessary for clinical analysis.

Since Yanagihara does not disclose a dry analytical element used in a dry process, Yanagihara does not disclose each and every claim element of the claimed invention. Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. § 102 (b) be reconsidered and withdrawn.

Rejection Based On Terashima In View of Hundt Under 35 U.S.C. § 103 (a)

The Examiner rejects Claims 1-3 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent 5,008,078 to Yaginuma et al. in view of U.S. Patent No. 6,395,325 to Hedge et al. Applicant respectfully traverse this rejection.

The Examiner asserts that Terashima discloses a dry analytical element for measuring the activity of alkaline phosphatase in a sample. The Examiner further asserts that Terashima discloses in example 6 that control human serums have known alkaline phosphatase in it and are spotted onto the dry analytical element and analyzed. The Examiner concedes that Terashima fails to teach that the control serums are frozen or freeze dried with no dialysis before used in testing the dry analytical element but the Examiner refers to Hundt to teach this deficiency in Terashima. Although the Examiner acknowledges that Hundt does not mention that the freeze dried control serum undergoes any dialysis process, the Examiner concludes that it would have been obvious to one of ordinary skill in the art at the time of the invention to freeze dry or lyophilized the control serum containing alkaline phosphatase taught by Terashima before its use in testing of a dry analytical element since Hundt teaches that control serums containing alkaline phosphatase are preferentially lyophilized for storage so as to maintain a prolonged viability. Applicants respectfully disagree.

To establish obviousness of a claimed invention, all claim elements must be disclosed, taught or suggested by the prior art. We agree with the Examiner that Terashima does not teach that the control serums are frozen or freeze dried with no dialysis before use in testing the dry analytical element. We also agree that Hundt does not mention that the freeze dried control serum undergoes a dialysis process.

Hundt teaches a control serum having a definite amount of alkaline phosphatase where the control serum is lyophilized to eliminate water from the serum. Although the control serum used in Examples 1-2 and 4-8 shows a control serum that is a commercial product that has been dialyzed, the human serum prepared in Example 3 is lyophilized without dialysis. Note that the fibrin has not been removed from the serum in Example 3. In other words, Example 3 discloses an experiment and the serum is not supplied as a commercial control serum. Examples 1-5 and 7 of Hundt illustrate what Hundt is claiming. Thus, Hundt does not teach the control serum of the invention. Further, Hundt does not teach the problem in the misfit of the analytical data obtained by using a dry analytical element from those obtained by wet processed, nor teach how to solve it.

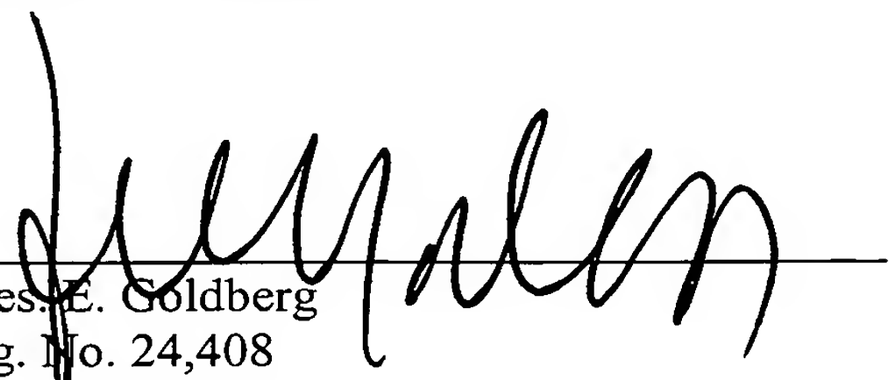
In contrast, the present invention claims a method of measuring a blood component in a dry analytical process using a dry analytical element and a control serum where the control serum is prepared from a serum from which fibrin has been removed but which has not been subjected to dialysis by freezing or freeze drying. Terashima does not disclose that control serums are frozen or freeze dried with no dialysis before use in testing the dry analytical element. Further, Hundt does not disclose this deficiency of Terashima.

Thus, the Applicant believes that the amended invention is not obvious over the teaching of Terashima in view of Hundt since Terashima and/or Hundt does not teach, disclose or suggest the present claims. Moreover, one skilled in the art would find nothing in Terashima or Hundt alone or in combination that would disclose, teach or suggest the claimed invention or any reason for making it. Further, there is no motivation to combine the references in such a way to get the claimed invention. Therefore, an obvious rejection under 35 U.S.C. §103 (a) is improper.

In view of the remarks presented herein, it is respectfully submitted that the present application is in condition for final allowance and notice to such effect is requested. If the Examiner believes that additional issues need to be resolved before this application can be passed to issue, the undersigned invites the Examiner to contact him at the telephone number provided below.

Respectfully submitted,

Dated: June 22, 2004

By 

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